UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL No. 1456** **Master File No. 01-12257-PBS**
	Judge Patti B. Saris
THIS DOCUMENT RELATES TO: **State of California, *ex rel.* Ven-A-Care v. Abbott Laboratories, *et al.*** **03-cv-11226-PBS**	

PLAINTIFFS' SUR-REPLY IN RESPONSE TO DEFENDANT ABBOTT LABORATORIES, INC.'S SEPARATE MOTION TO DISMISS THE FIRST AMENDED COMPLAINT

Respectfully submitted,
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Dated: April 17, 2006

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Abbott fails in its argument that the State violates the Dormant Commerce Clause when it sets at prevailing industry levels the amount that *it is willing to pay* for pharmaceuticals under its Medicaid program. The State is not required to stand by in silence when Abbott sets drug prices at up to ten times industry rates. Abbott's argument is predicated on the erroneous factual assumption that the term "direct price" had no meaning in the industry other than simply some number that it made up. Abbott knew that its reported direct prices were grossly inflated over its actual "direct prices," and its behavior constitutes one of the clearest and most egregious examples of fraud in this litigation.

I. PLAINTIFFS HAVE UNAMBIGUOUSLY ALLEGED THAT ABBOTT REPORTED FALSE DIRECT PRICES.

The First Amended Complaint ("FAC") unambiguously and clearly alleges that Abbott reported false direct prices for its pharmaceutical products in violation of the California False Claims Act. Abbott's argument is based on its erroneous contention that the term "direct price" had no meaning other than the number that Abbott chose to report to pharmaceutical pricing compendia, and in particular, that the term had no correlation to the prices that Abbott actually charged when it sold its drugs directly (rather than through wholesalers) to pharmacies. That contention as to industry usage is wrong. In the context of a motion to dismiss, Plaintiff is entitled to the common-sense inference that the term "direct price" means the price that Abbott actually charged for its drugs when it sold them directly to pharmacies (as distinct from the practice of most drug manufacturers of selling only through wholesalers, which required some mechanism to estimate the wholesalers' prices (e.g., AWP) in order to adequately reimburse pharmacies). Hence, when Abbott reported supposed "direct prices" that were ten times the amount at which it actually sold its drugs directly

to pharmacies, it defrauded the State.

Both on a national level and within the State of California, the Medicaid program was designed to provide adequate reimbursements so that drugs were available to participants, but at the same time "prevent pharmaceutical manufacturers from charging the government and taxpayers above-market prices for Medicaid drugs." *Pharmaceutical Research & Mfrs. of Am. v. Thompson,* 251 F.3d 219, 225 (D.C. Cir. 2001). That was the rationale for determining an "estimated acquisition cost" for drugs. Direct prices were used in that and related determinations where "a product [was] widely and consistently available at that price." 45 Fed. Reg., No. 208 at 70575 (1980).

Thus, in adopting the term "direct price" for its regulations, California followed the lead of HCFA and accepted industry usage. In short, as Abbott has long known, the California statutes and regulations used the term "direct price," consistent with industry usage, to mean the *actual market prices* that Abbott charged when it sold its drugs directly to providers, not some mythical "list price" that bore little, if any, relation to market prices. It is Abbott that, once caught committing pricing fraud, now seeks to redefine the term. By reporting purported "direct prices" that were in reality as much as ten times its actual market prices, Abbott defrauded the State and its taxpayers.

II. CALIFORNIA'S REGULATION OF THE AMOUNT AT WHICH IT REIMBURSES PROVIDERS FOR DRUG PRODUCTS DOES NOT VIOLATE THE DORMANT COMMERCE CLAUSE.

As discussed above, California's use of the term "direct price" was not an attempt to "hijack and redefine" industry standards, as Abbott argues, but rather was an effort to follow them. Hence, it is clear under *Pharmaceutical Research & Mfrs. of Amer. v. Concannon,* 249 F.3d 66 (1st Cir. 2001), *aff'd*, 538 U.S. 644 (2003), that California's reimbursement system does not offend the

Dormant Commerce Clause.[1]

First, although the *Concannon* court found the market participant exemption inapplicable to the Maine statute at issue, the court made clear that its holding did not apply to the extent that the state was a "buyer of prescription drugs" under the Medicaid statute. *Id.* at 80. Contrary to Abbott's arguments, *Concannon* did not distinguish between situations where the State purchased drugs as opposed to reimbursing others. Rather, the market participant exemption was inapplicable there because Maine was trying to control the prices that "Maine citizens who were *not* Medicaid recipients" had to pay for drugs. *Id.* at 71 (emphasis added). That rationale is inapplicable here.

Second, even if this Court were to find the market participant exemption inapplicable, the *Concannon* court's analysis makes clear that enforcement of the California False Claims Act under the circumstances here would not offend the Constitution. The California reimbursement system did not dictate the amount that persons in other states would pay for Abbott's products or even limit the dollar amount that Medi-Cal would pay for Abbott's drugs; rather, California provided simply that it would reimburse at the "direct prices" that Abbott actually charged its customers. That minimal degree of regulation did not discriminate against or impose excessive burdens on commerce.

CONCLUSION

As Abbott concedes, "California has latitude to reimburse for drugs based on its estimation of what providers pay (*see* 42 C.F.R. § 447.301)." Abbott Reply Mem. at 3. The State's use of the term "direct price" attempted to do just that, and Abbott's motion should be denied.

[1]Under the Medicaid Act, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v (2000), the federal government provides financial support to states that establish and administer state Medicaid programs in accordance with federal law through a state plan *approved by* the U.S. Department of Health and Human Services ("HHS"). 42 U.S.C. § 1396 (2000); 42 C.F.R. §§ 430.0, 430.10-.20 (2002). One requirement is that the state have a scheme for reimbursing health care providers. 42 U.S.C. §§ 1396a(a), 1396d(a) (2000). California's reimbursement plan has been approved, of course, by HHS at all times relevant to the FAC.

CERTIFICATE OF SERVICE

I, Nicholas N. Paul, hereby certify that on April 17, 2006, I caused a true and correct copy of the foregoing, **PLAINTIFFS' SUR-REPLY IN RESPONSE TO DEFENDANT ABBOTT LABORATORIES, INC.'S SEPARATE MOTION TO DISMISS THE FIRST AMENDED COMPLAINT** to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

Dated: April 17, 2006

/s/ Nicholas N. Paul
NICHOLAS N. PAUL
Supervising Deputy Attorney General